# Grant Application Checklist

When creating a grant application especially for a federal agency opportunity, it's important to get the most out of the opportunity you are applying for. Use this list of common elements included in research grant applications and budgets to ensure you've considered all the necessary resources in your proposal.

| Institutional Review Board (IRB) | Y/N |
|---|---|
| Does your funding source require single IRB (sIRB) oversight? | |
| If sIRB oversight is required, is your local IRB able to provide this? Or do you need to look outside the institution?<br>• Most federally funded studies that involve multiple sites, including collaborative research studies, must now use a sIRB for all sites.<br>• Some institutional IRBs do not have the operational resources to support multisite studies, or do not have the capacity to provide fast turnaround times to support your study's goals. | |

**Learn about Advarra's IRB services** **Start the IRB reliance agreement process**

| Data Monitoring Committee (DMC) / Data Safety Monitoring Board (DSMB) | Y/N |
|---|---|
| If any of the following are true for your study, you may need to include a DMC in your plans:<br>• The study endpoint is such that a highly favorable or unfavorable result (or finding a futility at interim analysis) might ethically require study termination before its planned completion.<br>• There are reasons for a particular safety concern (e.g., if the procedure for treatment administration is particularly invasive).<br>• There is prior information about the study treatment suggesting the possibility of serious toxicity.<br>• The study is performed in a potentially fragile population, such as children, pregnant women, the very elderly, people who are terminally ill, people of diminished mental capacity, or other vulnerable populations.<br>• The study is performed in a population at elevated risk of death or other serious outcomes (even when the study objective addresses a lesser endpoint).<br>• The study is large, of long duration, blinded, or multi-center/multi-national and would benefit from additional oversight. | |
| Does your institution have capacity to support a DMC for the duration of the trial?<br>• Will you have access to the expertise necessary for this particular study?<br>• Will that DMC be appropriately independent from study conduct? Per FDA and EU EMA guidelines, independence is a critical element. | |

**Learn about Advarra's DMC services**

| Institutional Biosafety Committee (IBC) | Y/N |
|---|---|
| NIH Guidelines require IBC oversight if the following apply:<br>• The research involves the use of recombinant DNA (rDNA), including messenger RNA (mRNA), synthetic nucleic acid (sNA) molecules, or other genetically engineered treatments, AND<br>• Either the site or the sponsor has received NIH support for rDNA or sNA research in the past, or is currently conducting NIH-supported studies involving rDNA or sNA.<br>• This includes sites and sponsors outside of the United States.<br>• Even if there is no NIH support involved, IBC review is a best practice per NIH Guidelines Section IV-D-1. | |
| Does your institution have a local IBC who can provide clinical trial oversight?<br>• Many local IBCs focus primarily on preclinical and nonclinical research.<br>• Advarra coordinates IRB and IBC review to streamline startup processes. | |

Learn more about IBC oversight | Learn about Advarra's IBC services

| Endpoint Adjudication Committee (EAC) / Clinical Event Committee (CEC) | Y/N |
|---|---|
| Your study may require an EAC if:<br>• Trial endpoints are complex, and some degree of medical judgment is needed to determine if a participant has met a protocol-defined endpoint.<br>• Specific therapeutic expertise is needed beyond that of the principal investigator or sponsor's medical monitor. | |
| Does your institution have capacity to support an EAC for the duration of the trial?<br>• Will you have access to the expertise necessary for this particular study?<br>• Will that EAC be appropriately independent from study contact? Per FDA and EU EMA guidelines, independence is a critical element. | |

Learn about Advarra's EAC services

| Protocol Development and Informed Consent Form (ICF) Writing Services | Y/N |
|---|---|
| Who will develop the protocol and ICF for the trial?<br>• Do your internal resources have sufficient time to commit to providing this support?<br>• Do your internal resources have the appropriate skills and knowledge to prepare a protocol and consent that will help achieve study goals and meet local and federal regulatory requirements?<br>• Developing these documents requires specialized knowledge, not only of the trial itself but also of the applicable regulatory requirements. It also requires dedicated time to write a protocol and ICF, sometimes weeks or more. | |
| Do you have access to template tools that might inform development of these documents?<br>• Note that not all studies will easily "fit" into existing standard templates. | |

Learn about services for protocol and ICF development

| Site Identification Support | Y/N |
|---|---|
| If planning a multisite study, do you know which investigators/sites you'll invite to participate?<br>• Do you know if those investigators/sites are equipped to conduct your study? Think not only of expertise but also about access to specific equipment or techniques.<br>• Do you know if those investigators/sites will be able to recruit enough participants?<br>• What do you know about the past study experience for your preferred investigators/sites?<br>• It's commonly stated that activating a research site costs around $50,000 on average. If the site fails to recruit a single participant, those funds are effectively wasted. | |

Learn about SiteIQ site identification insights

| Research Staffing | Y/N |
|---|---|
| Have you already secured commitments for the dedicated roles your study will require?<br>• Bear in mind: Your local staffing situation may be different by the time your study requires support from these roles.<br>• It may be prudent to future-proof your trial by requesting funds to staff certain key roles:<br>– Clinical research coordinators<br>– Regulatory coordinators<br>– Director of clinical operations<br>– Clinical research nurse<br>– Project managers<br>– Data specialists<br>– Study activation coordinators | |

Learn about Advarra's research staffing solutions

| Consulting | Y/N |
|---|---|
| Do you have access to appropriate expertise for all aspects of your proposed trial? Consider:<br>• Data privacy practices management<br>• Data sharing and material transfer management<br>• Clinical trial monitoring<br>• Research technologies evaluation and implementation<br>• Policy/standard operating procedure gap analysis and development<br>• Determine U.S. and international regulatory pathways and requirements<br>• Pre-IND meeting briefing package<br>• Current FDA requirements<br>• FDA meetings<br>• Regulatory operations:<br>– IND, NDA, ANDA, BLA applications<br>– Technical writing/CMC documentation<br>– eCTD publishing | |

Learn about Advarra's global consulting services

**Please note:** This list is not all-inclusive and is designed to be a starting point for conversations at your organization. We recommend confirming requirements with the funding source and/or your local research program.